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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,092	02/06/2004	Ernesto A. Brovelli	AM1150	7125

28533 7590 12/13/2007

IN RE: ALTICOR INC. 28533
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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,092	BROVELLI ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-7 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-7 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3, 5-7 and 23-25 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Applicants' cancellation of claim 1 has rendered moot the previous rejection under 35 USC 112 First paragraph.

Claim Objections

Claim 3 is objected to because of the following informalities: Upon preparing the amendment to claim 3, it appears that Applicants inadvertently omitted the period (.) at the end of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 3, 5-7 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claims 3 and 24 to read " ...(i) a concentration of marker compound that is greater than zero and acceptable for preparing a standardized extract of the medicinal plant..." (respectively).

It is determined that the phrase 'greater than zero' is New Matter. While Applicants have indicated several concentrations of marker compounds upon harvesting Echinacea plants, the phrase 'greater than zero' indicates a range of zero to 100%. Because this range was not originally disclosed, it is deemed that Applicants were not in possession of this range. Because claims 5-7 and 24-25 depend upon either claims 3 or 24 respectively, claims 5-7 and 24-25 necessarily contain all of the limitations of either claims 3 or 24 respectively and therefore also contain New Matter and are appropriately rejected under this statute.

Claims 3, 5-7 and 23-25 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicants regard as the invention for the reasons set forth in the previous Office Action.

Applicant has amended claims 3 and 24 to read " ...(i) a concentration of marker compound that is greater than zero and acceptable for preparing a standardized extract of the medicinal plant..." (respectively).

Applicants' arguments were fully considered, but not found persuasive. Applicants argue that the MPEP states "[a]cceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.' As amended, the claims are not indefinite because one of ordinary skill in the art will know what levels of a marker are greater than zero and acceptable for preparing a standardized extract" (p. 6, Remarks). However, the metes and bounds of the claim are not clear in that the Specification does not teach what an acceptable level of marker compound is. Further, the claim can be directed toward trace amounts of a marker compound (please note that claim 5 is the only claim directed toward specific markers). Is a trace amount an 'acceptable' amount of marker? The question is, would one of ordinary skill in the art reasonably understand the metes and bounds of Applicants' invention? For example, consider the ordinary artisan; perhaps having a PhD in horticulture who is preparing an extract of Echinacea and determines that this extract contains 0.5% chlorogenic acid. Is this amount of chlorogenic acid 'acceptable' for standardization of the extract? The ordinary artisan would not know, and would

never know if they are infringing upon the claims because Applicants have not communicated what they deem an 'acceptable' amount of marker.

Applicants argue "Any concentration of chicoric acid greater than zero may be acceptable for preparing a standardized Echinacea extract so long as all extracts from a single source...are prepared so that they have the same concentration of chicoric acid" (pp. 6-7, Remarks). However, these remarks are not found in the Instant disclosure as filed. Applicants may, at this time, cite their original intent for the meaning of 'acceptable' in regard to marker compounds; however, it is not seen where Applicants have clearly disclosed in the specification what they deem to be an 'acceptable' amount of marker compound.

Applicants again argue that Table 1 and paragraphs 22 and 24 show that chicoric acid levels do not vary greatly between maturation stages. "Hence," Applicants argue, "in one example, a concentration of marker compound that is greater than zero and acceptable for preparing a standardized Echinacea extract may be 3.5% chicoric acid, that standardization level is acceptable" (p. 7, Remarks).

However, to reiterate from the previous Office action:

> Here, it is not clear that Applicant has disclosed what an acceptable amount of chicoric acid levels would be. Rather, it is only determined from this statement that the variation of chicoric acid levels is what is accepted. In the claims, Applicant is attempting to claim a particular range of concentrations of marker compounds (it is noted that the claims are

not limited to chicoric acid) including chicoric acid, however, it is not clear what the amount (or range) of chicoric acid or any other marker compound is. (see page 5, previous Office action)

Applicants further argue that "The same would be true of the extract were standardized to 3.4% or 3.6% chicoric acid, or even some other concentration percentage were selected" (p. 7, Remarks). However, again, Applicants' contentions were not disclosed in the original Specification as filed. Thus, the ordinary artisan would not know if they were infringing on the invention and hence, the claim language is deemed indefinite.

Claim 3 is rejected under this statute for the recitation of 'the medicinal plant' in part (i). This phrase lacks antecedent basis in the claim as amended. A suggestion to overcome this rejection is to replace 'the medicinal plant' with 'the Echinacea.'

Claim Rejections - 35 USC § 103

Claims 3, 5-7 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C or B in view of C; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract) and C= Rininger et al. (2000). Seidler –

Lozykowska et al. may be referred to as SL et al for the reasons keenly discussed in the previous Office Actions.

Applicants' arguments were fully considered, but not found persuasive.

Applicants argue:

...according to Section 2141 of the MPEP, when applying 35 U.S.C. 103, the following tenents of patent law must be adhered to: (A) The claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight...; and (D) reasonable expectation of success is the standard with which obviousness is determined. Hodosh v. Block Drug Co., Inc...Applicants thus comment that "Under these standards, the claims are not obvious in view of the cited references. First the claimed invention as a whole is a method for determining optimal harvest window of Echinacea, based on selecting a plant maturation stage that has both a concentration of a marker compound that is greater than zero and acceptable for preparing a standardized extract, and immonostimulatory activity. the claimed method also includes a step of preparing a standardized extract at that selected maturation stage.

Applicants further argue that:

"[t]he cited references as a whole do not teach this method....Seidler-Lozykowska and Dou, examine when the greatest levels of typical marker compounds...used to standardize extracts may be obtained from which specific parts of the plant....Rininger, teaches that standardized Echinacea extracts are 'inactive' for immunostimulatory activity. Rininger also teaches that compounds commonly used to standardize

> Echinacea...do not possess any immunostimulatory activity....Rininger further teaches that *non-standardized* Echinacea, specifically Echinacea herb and root powders, was found to be immunostimulatory...Rininger teaches that although Echinacea may possess imunostimualtory activity, ***standardized*** extracts of Echinacea do **not** possess any such activity"

It is noted that the Examiner has based her rejections upon the 'Graham inquiries; that is:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Based upon these factors, it is determined that the claimed invention as a whole is obvious in view of the combination of the cited prior art references for reasons keenly pointed out in previous Office actions, as well as herein.

Claim 3 for example, is directed toward a method for preparing a standardized Echinacea extract which includes:

1) harvesting at least one Echinacea plant at a plurality of maturation stages for the Echinacea plant,

2) producing a preparation of the Echinacea plant for each maturation stage;

3) adding a preparation to a monocyte cell culture;

4) harvesting the cell culture,

5) analyzing the cell culture for a level of immune-stimulatory product,

6) determining a concentration of a marker compound in each maturation stage, and

7) selecting a maturation stage with: a concentration of marker compound that is greater than zero and acceptable for preparing a standardized extract of the medicinal plant and the highest level of immune-stimulatory product.

It is noted that the prior art does not specifically teach all of the claim limitations in one reference, hence, there is no 102 rejection. However, the invention as a whole is rendered obvious by the prior art references. Echinacea plants were well-known in the art at the time the invention was made and exhaustively studied for their medicinal effects. The claimed invention as a whole is obvious, and there is no individual step in any of the method claims which was not already known or made obvious by the prior art. That is, there is no novel step or idea in the method claims which makes it unobvious over the prior art references. According to the prior art references, as keenly pointed out in the previous Office action, Echinacea plants were known to be studied at different maturation stages for marker compounds to select for optimum levels of compounds. Echinacea plants were also known to contain immunopotentiating activity, and the activities were known to be studied and already determined to depend, in part, upon the harvesting time of the Echinacea. Additionally, Applicants' method for determining the level of immunopotentiating activity, as well as marker immuno stimulatory products were known in the art at the time the invention was made. While no one, individual reference taught all of these steps

together; the ordinary artisan would have been motivated to perform the claimed method in order to optimize medicinal efficacy of an Echinacea extract and standardization would have been routine in manufacturing extracts with essentially uniform chemical constituents and hence, medicinal effectiveness: ***"[a] person of ordinary skill is also a person of ordinary creativity, not an automaton*** *KSR* 127S. Ct. at 1742 (emphasis added).

The desirability of creating Echinacea extracts with increased immunopotentating activity, as well as increased levels of compounds such as chicoric acid was *well-documented in the art* (see cited references). It is deemed that the method claims of the Instant invention would have been well-within the purview of the ordinary artisan at the time the invention was made having the above-cited references before him or her. One of ordinary skill in the art would have had a reasonable expectation of success in choosing an Echinacea plant with 'the highest' amount of immuno-stimulatory' activity and at least some amount of chicoric acid because both immuno-stimulatory activity as well as chicoric acid were desired at the time the invention was made.

While Applicants argue that Rininger...teaches that standardized extracts are "inactive" for immunostimulatory activity...[and] that the compounds commonly used to standardize Echinacea extracts, e.g., chlorogenic acid, do not possess any immunostimulatory activity...[and] that *non-standardized* Echinacea, specifically Echinacea herb and root powders, was found to be immunostimulatory....***standardized***

extracts of Echinacea do **not** possess any such activity" it is determined that Applicants have over-generalized the Rininger reference, and thus, have respectfully misinterpreted its teachings. As pointed out in the previous Office action, Rininger *only teaches that the 4% phenolic standardized extracts did not induce macrophage stimulation (see page 8). This does not indicate that all extracts from Echinacea standardized for chicoric acid will be inactive for immunopotentiating activity. Furthermore, Rininger* ***explicitly*** *teaches that polysaccharides from Echinacea* ***do have*** *immunopotentiating activity; polysaccharides* ***being one of the marker compounds specifically claimed by Applicants.***

In either respect, it is deemed that it would have been obvious to select for a marker compound such as polysaccharides or chicoric acid because these marker compounds *were known to have medicinal activity and hence were desirable.*

Applicants contend that "...one of ordinary skill in the art would not, based on the teachings of the cited references, expect the claimed method of optimizing harvest window of a plant, e.g., Echinacea, by selecting a plant maturation stage that produces a level of marker compound acceptable for preparing a standardized extract, yet also maintains immunostimulatory activity, to be successful" (p. 9, Remarks). However, the Examiner respectfully disagrees. It is determined that the prior art has set forth ample information in order to guide the ordinary artisan to select an optimum harvest window

of Echinacea which possesses the greatest immunopotentating activity as well as marker compounds such as polysaccharides and chicoric acid.

Applicants compare the outstanding rejection to *In re Grasselli* and indicate that "The claims are to a method that involves combining two characteristics of Echinacea: (1) standardization of the plant ("S") and (2) immuno-stimulatory activity of the plant ("ISA")...Two references, Seidler-Lozykowska and Dou teach maximizing levels for S while the third reference Rininger teaches that standardized Echinacea extracts do not have immunostimulatory activity. Thus, the combined teaching is that if an Echinacea extract is standardized, then it does not have immonostimulatory activity". Again, this argument is based upon ***Applicant's misinterpretation and over-generalization of the Rininger reference*** in that ***Rininger did not teach that standardized extracts do not contain immunopotentating activity.*** Rininger merely taught that the extracts which were purchased for testing which contained 4% of phenolic compounds were inactive for induction of macrophage cytokine production. It would be absolutely expected that an extract of Echinacea which is standardized for immunopotentiating activity such as standardization for polysaccharides from Echinacea purpurea (see p. 2, Rininger) *will have immunopotentiating activity*. Further, Applicants are not indicating in the claims that the extracts are standardized for a marker compound, merely that a marker compound is present in the extract.

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...
>
> ...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith

Primary Examiner
Art Unit 1655

December 7, 2007